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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,714	10/01/2001	Caroline J. Springer	620-162	7025

7590 01/27/2004

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EXAMINER

OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,714

Applicant(s)

SPRINGER ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-97 and 100-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-55, 66-83, 87-89, 91 and 100-102 is/are rejected.
- 7) ☒ Claim(s) 56-65, 84-86, 90 and 92-97 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/1/2001.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

The Status of Claims :

Claims 48-97 and 100-102 are pending.

Claims 48-55 ,66-83, 87-89, 91 and 100-102 have been rejected.

Claims 1-47 and 98-99 have been canceled.

Claims 56-65, 84-86, and 90, and 92-97 have been objected.

DETAILED ACTION

1. Claims 48-97 and 100-102 have been under consideration.

Priority

2. This application is a 371 of PCT/GB00/01194 filed on 03/29/2000.

Drawings

3. The drawing filed on 10/1/2001 is accepted by the Examiner.

Election/Restrictions

Applicant's election without traverse of Group II (claims 48-97 and 100-102) on 10/14/2003 is acknowledged. Claims 98-99, drawn to the two component system and the kit withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to the nonelected Groups I and III, there being no allowable generic or linking claim. Election was made **with** traverse on 10/14/2003.

Claim Rejections - 35 USC § 112

Claims 100-102 are rejected under 35 U.S.C. 112, first paragraph. Claims 100-102 are composition claims for treating cancers. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without **undue experimentation**.

Attention is directed to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation, citing *Ex Parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,

- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breath of the claims.

With respect to the state of the prior art, the specification falls short because data essential for treating cancers is not described in the specification. In the absence of specific malignant tumors or otherwise, data showing inhibition of the multiplication of cancer cells, such a broad assertion is not believable in view of the contemporary knowledge of the art. 34 USPQ 2d, 1436 (Fed Cir. 1995) . See also, MPEP 2107.01, 2107.02, 2107.03, 2164.01©, 2164.04, 2164.07.

Moreover, the claim sets forth the treatment of cancer generally. However, there are more than 3000 cancers. Applicants have not identified a specific compound capable of treating “cancers” broadly. Thus, the existence of such a “silver bullet” is contrary to our present understanding in oncology. Even the most broadly effective anti-tumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body’s cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, regarding the necessary quantity of experimentation, it is beyond the skill of oncologists today to get an agent to be effective against cancers

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generally, evidence that the level of skill in this art is low relative to the difficulty of such a task. See also, *In re Joller*, 206 USPQ 885 (CCPA 1980).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

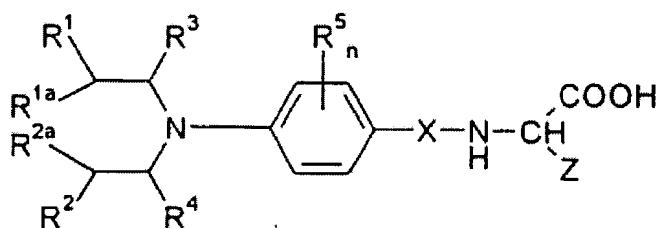
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 48-55, 66-83, 87-89, 91 and 100-102 are rejected under 35

U.S.C. 102(b) as being anticipated clearly by Springer et al (WO94/25429).

Springer et al (WO94/25429) discloses nitrogen mustard compounds of the following formula, where X is $-\text{C}(=\text{O})$; Z is $(\text{CH}_2)_2-\text{COOH}$ or $(\text{CH}_2)_2-\text{CO}_2\text{C}(\text{CH}_3)_3$; R^5 is F (See page 12, Ex. 7 and 8).



Furthermore, specific examples of the chemical compounds (4-12) are shown on page 12. These compounds can be useful as pro-drugs for treating cancer (see page 11, lines 20-22). This is identical with the claims.

2. Claims 87-89, and 91 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Cozzi et al (WO97/03957).

Cozzi et al (WO97/03957) teaches 3-methyl-4N,N-bis(2-chloroethyl)aminobenzylic acid (see page 13, lines 1-2) , which can be used in a treatment to ameliorate a cancer (see page 14, lines 5-6). This is identical with the claims.

3. Claims 87-89, and 91 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Karpavicius et al (Izvestiya Akademii Nauk SSSSR, 1979, (1), p. 51-8) .

Karpavicius et al discloses 4-bis(2-chloropropyl)amino-benzoic acid (see abstract page). This is identical with the claims.

4. Claims 87-89, and 91 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Karpavicius et al (Poiski Izuch. Protivopukholevykh, 1977, 66-75) .

Karpavicius et al discloses 4-bis(2-chloropropyl)amino-benzoic acid (see abstract page). This is identical with the claims.

5. Claims 87-89, and 91 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Ivanova et al (Leikozoologiya, 1975, 4, 23-9) .

Ivanova et al discloses 4-bis(2-chloropropyl)amino-benzoic acid (see abstract page). This is identical with the claims.

6. Claims 87-89, and 91 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Prasmickiene et al (Izvestiya Akademii Nauk SSSSR, 1969, (3), p. 643-6) .

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Prasmickiene et al discloses 4-bis(2-chloropropyl)amino-benzoic acid (see abstract page). This is identical with the claims.

7. Claims 87-89, and 91 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Jen et al (Huaxue Xuebao, 1965, 31(6), p. 486-92, 500) .

Jen et al discloses 4-bis(2-chloropropyl)amino-benzoic acid (see abstract page). This is identical with the claims.

8. Claims 87-89, and 91 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Davis et al (Journal of the chemical Soc., 1950, p. 1331-7).

Davis et al discloses 4-bis(2-chloropropyl)amino-benzoic acid (see abstract page). This is identical with the claims.

Claim Objections

Claims 56-65, 84-86, and 90, and 92-99 are objected to as being dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 703-305-0809. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone number for the organization where this application or proceeding is assigned is 703-308-2742.

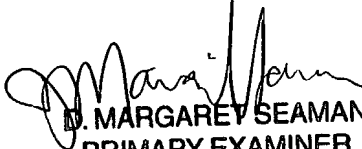
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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1/21/04


D. MARGARET SEAMAN
PRIMARY EXAMINER